In the Office Action, the Examiner indicated that claims 1-43 were withdrawn from further consideration pursuant to 37 C.F.R. § 1.142(b). The Examiner acknowledged that Applicants did timely traverse the rejection (election) requirement in Paper No. 5. However, the Examiner alleges that Applicants' arguments related to an Examiner who did not restrict the claim in the instant case in the national stage of a PCT application. Further, the Examiner alleges that Applicants did not particularly traverse the requirement on the grounds set forth in the instant case, specifically PCT Rules 13.1 and 13.2.

Contrary to the Examiner's allegation, Applicants did specifically traverse the restriction requirement on grounds set forth specifically under PCT Rules 13.1 and 13.2 as implemented in U.S. patent practice as 37 C.F.R. §§ 1.142(b), 1.45, 1.475 and 1.499. (See October 22, 2002 Amendment, pages 1-3.) Further, Applicants specifically argued that there was a single general inventive concept uniting the claims of Groups I, II and III in accordance with the standard set forth under 37 C.F.R. § 1.475(b)(3) (October 22, 2002 Amendment, pages 2-3).

Specifically, in the October 22, 2002 Amendment, Applicants argued that the present application, claims 1-18 of Group I are drawn to a product, namely an adhesive, the use of that adhesive product (Group II, claims 19-43), a product which comprises the adhesive product (Group III, claims 44-53), and a method of using the adhesive product (claim 54) (October 22, 2002 Amendment, pages 2-3). Therefore, Applicants argued that under 37 C.F.R. § 1.475(b)(3), the subject matter of Groups I, II and III share the same inventive concept, i.e., an adhesive composition, a method of manufacturing the composition and a method of using the new an novel composition,

and thus establishing a unity of invention among the claims of Groups I, II and III (October 22, 2002 Amendment, page 3).

Based on the foregoing discussion, Applicants respectfully submit that in the October 22, 2002 Amendment, Applicants did particularly traverse the requirement on the grounds set forth in the instant case with regard to PCT Rules 13.1 and 13.2 as implemented by U.S. patent practice. Therefore, Applicants respectfully request that the Examiner reconsider the Restriction Requirement and withdrawing claims 1-43 from consideration pursuant to 37 C.F.R. § 1.142(b). Accordingly, Applicants respectfully request that the Examiner reinstate claims 1-43.

Claims 44-54 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Stroetmann. Without addressing the merits of the Examiner's rejection and in order to move this case to allowance, Applicants have amended claim 44 to more clearly and succinctly recite what Applicants believe to be the invention. Claim 44 now more clearly recites how the protein and gas are contained. Support for the amendment to claim 44 can be found in the specification as filed on page 19, lines 10-24, 29-34 and page 23, lines 11-13, 19-22. Therefore, the amendment to claim 44 does not constitute new matter.

Accordingly, claim 44 (currently amended) is now directed to a kit for preparing a biocompatible fluid adhesive protein foam as a dry preparation having a foam-like and fleece-like structure adapted for use as a wound toilet material, filling material for bone cavities and/or supporting material for further active substances, consisting essentially of thrombin in an at least catalytically active amount, fibrin and fibrinogen.

Turning now to the cited prior art of Stroetmann, Stroetmann merely discloses a supporting system of a fibrin mixture foam (Stroetmann, column 13, line 47). This foam is obtained by polymerization and cross-linking followed by deep-freezing (Stroetmann, column 10, lines 14-22) and lyophilization (Stroetmann, Example 1, column 14).

Further, Stroetmann discloses that in a case that a lighter material is desired, an inert propellant (nitrogen, carbon dioxide) can be blown into the solution prior to applying the material to a freeze-drying mold (see Stroetmann, column 10, lines 37-38 and 45-49).

Stroetmann fails to provide an enabling disclosure to make the claimed invention obvious. While Stroetmann *may* disclose the use of such an inert propellant, Applicants respectfully note that this process in not enabled by Stroetmann; Stroetmann fails to include a single example of putting this process into practice. Moreover, the general disclosure of Stroetmann does not provide any sufficient teaching to enable one of ordinary skill in the art to practice this step. Furthermore, Stroetmann fails to disclose or suggest any adhesive property with respect to a foam.

In sharp contrast to that of Stroetmann, the present claims are directed to a kit for preparing a <u>fluid adhesive</u> protein foam comprising an adhesive protein, a polymerization/cross-linking agent, a gas and means for extemporaneously mixing the constituents, whereby the foam is obtained in a ready-to-use form.

The Examiner alleges that the present claims would have been obvious in view of the kit implicitly disclosed in Stroetmann. Further, the Examiner asks how the gas and the fibrin are contained within the presently claimed kit.

Applicants submit that the present invention is distinct from Stroetmann in that no freeze-drying and lyophilization means or mold are required whereas Stroetmann clearly teaches freeze-drying and lyophilization are necessary steps in its process. Moreover the present foam is obtained after mixing the ingredients and the foam is in a ready-to-use form.

Furthermore, the presently claimed kit offers advantages over the one disclosed in Stroetmann in that no further step is required after combining the constituents, as the foam obtained with the present kit is fluid and adhesive. Stroetmann clearly does not suggest a kit for preparing a foam which is fluid and adhesive. Moreover, the present foam is fluid, suitable for application as formed whereas Stroetmann clearly discloses further articles are necessary to support the active ingredients. As a result, the present claims are novel and not suggested by the prior art.

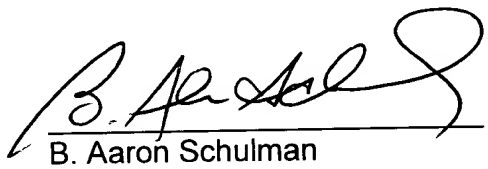
In summary, the kit of Stroetmann differs from the presently claimed kit as Stroetmann includes freeze-drying, lyophilization means, and a mold whereas in the present case, the foam is obtained in a ready-to-use form after mixing the ingredients. Based on the foregoing discussion, Applicants respectfully submit that claims 44-54 are not obvious in view of Stroetmann. Therefore, Applicants respectfully request that the Examiner withdraw the rejection to claims 44-54 under 35 U.S.C. § 103(a).

By this Amendment, Applicants have added new claim 55 based on original claim 50 and therefore, Applicants submit that claim 55 is not obvious from Stroetmann for at least the same reasons as discussed above with regard to claims 44-54.

In view of the foregoing discussion, Applicants respectfully submit that the present application is in condition for immediate allowance.

Respectfully submitted,

LARSON & TAYLOR, PLC



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March 26, 2003

## ATTACHMENT A
## Amendments to the Abstract

A marked up copy of the replaced Abstract is provided.

ABSTRACT

A biocompatible fluid adhesive protein foam, which is bioresorbable and nontoxic, for surgical and/or therapeutic use, in particular for protecting/cicatrizing tissue wounds and for attaching biological tissues to each other or to an implanted biomaterial. The biocompatible fluid adhesive protein foam includes a biocompatible fluid adhesive protein matrix, which is bioresorbable and nontoxic, containing a biocompatible and nontoxic gas or mixture of gases. Further, a process and a kit for preparing such a foam are provided.

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## ATTACHMENT B
## Amendments to the Claims

Following herewith is a complete listing of the claims, including a marked copy of the currently amended claims.

1-43. (Withdrawn)

44. (Currently Amended) A kit for preparing a biocompatible fluid adhesive protein foam, which is bioresorbable and nontoxic, for surgical and/or therapeutic use, in particular for protecting/cicatrizing tissue wounds and attaching biological tissues to each other or an implanted biomaterial, said kit comprising:

- a first container containing a potentially adhesive protein compound which can be polymerized/crosslinked, solubilized in aqueous medium, and, optionally, a biocompatible and nontoxic gas or mixture of gases;
- a second container containing a polymerization/crosslinking agent for forming a biocompatible fluid adhesive protein matrix, which is bioresorbable and nontoxic, and optionally, a biocompatible and nontoxic gas or mixture of gases;
- optionally a third container containing the whole or part of the biocompatible and nontoxic gas or mixture of gases; and
- means for extemporaneously mixing the constituents, protein compound in aqueous solution and polymerization/crosslinking agent for forming the adhesive matrix, and, optionally, the gas or mixture of gases;

whereby the protein foam is obtained in a ready to use form.

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45. (Currently Amended) The kit of claim 44, wherein the first container contains the potentially adhesive protein compound in pulverulent, dehydrated and optionally in a sterilized form, the second container contains an optionally sterile buffered aqueous solution, and wherein the kit further comprises means for supplying a polymerization/crosslinking agent to the solubilized protein compound and means for mixing the content of the first and second containers, and means for using a gas in the mixture and producing the foam.

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Deleted: and means for extemporaneously mixing the constituents, protein compound in aqueous solution and

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46. (Currently Amended) The kit of claim 44, wherein the polymerization/crosslinking agent is a reactive polymer and the gas is selected from air, nitrogen, oxygen and carbon dioxide or the mixture of one or more of these gases.

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Deleted: , preferably from air, carbon dioxide and nitrogen, air being most particularly preferred

47. (Currently Amended) The kit of claim 44, wherein the kit is in the form of two syringes equipped with mixing means, in which one of the syringes contains the protein compound in aqueous solution and the other contains the polymerization/crosslinking agent.

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48. (Currently Amended) The kit of claim 44, wherein the gas is combined with the protein compound and/or with the polymerization/crosslinking agent.

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49. (Currently Amended) The kit of claim 45, wherein the mixing means make it possible to pass the mixture from one syringe to the other several times so as to ensure the formation of the foam using the gas included in the syringe containing the pulverulent protein compound.

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50. (Currently Amended) The kit of claim 44, wherein the gas is combined with a biocompatible and nontoxic vehicle.

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51. (Currently Amended) The kit of claim 44, further comprising a third syringe containing the gas optionally combined with a vehicle.

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52. (Currently Amended) The kit of claim 51, wherein the vehicle also contains one or more biologically active substances.

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53. (Currently Amended) The kit of claim 44, wherein the polymerization/crosslinking agent and/or the vehicle is in lyophilized form.

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54. (Previously Amended) A method for using a fluid adhesive protein foam as claimed in claim 1 for:

preventing or stopping the bleeding of vascular or tissue wounds;

attaching biological tissues including live tissues to each other or to an adjacent biomaterial;

cicatrizing surgical or chronic wounds;

protecting or sealing sutures;

C2 preventing the formation of postoperative adhesions;

delivering biologically active substances for local application; and

filling tissue cavities.

55. (New) The kit of claim 50, wherein biocompatible and nontoxic vehicle is formed from a protein compound which comprises a protein or a mixture of proteins selected from collagen, gelatin, albumin, elastin and fibrinogen.